IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI

DALE L. RAGGIO, JR., ANNE BECKNER, MATTHEW SPRING, ROBIN ANDERSON AND LEANNE MATUSEK, *on behalf of himself and all other similarly situated persons*,	§	**C.A No. _____**
Plaintiffs,	§	**JURY TRIAL DEMANDED**
vs.	§	
MEAD JOHNSON COMPANY,	§	
Defendant.	§	

CLASS ACTION COMPLAINT

Plaintiffs, by their attorneys, bring this class action against Mead Johnson Company ("Mead Johnson" or "Defendant") on their own behalf and on behalf of a class of all other similarly situated persons (the "Class"), including all persons who purchased infant formula packaged in metal cans lined with epoxy resins containing Bisphenol-A (2,2-bis (4-hydroxyphenly)-propane) ("BPA"), and produced, manufactured, sold and/or distributed by Defendant hereinafter referred to as ("Contaminated Formula Products"). Plaintiffs bring this action for compensatory and equitable, injunctive and declaratory relief against Defendant for violation of various state deceptive trade practices acts, breach of warranty, misrepresentation and unjust enrichment. Plaintiffs allege upon personal knowledge matters pertaining to themselves and their own acts, and as to all other matters, upon information and belief, based upon the investigation undertaken by their counsel:

I. SUMMARY OF THE ACTION

1. This action arises out of Mead Johnson's misrepresentations and/or omissions and failure to warn of and/or otherwise disclose or adequately disclose that its Contaminated Formula Products are manufactured using a dangerous chemical that has been known for years to be toxic in several respects and which poses serious risks to an individual's health due to the fact that it leaches into food and beverages in the normal course of everyday use. Despite well-documented scientific evidence of the harmful effects of BPA on infants and children, Mead Johnson marketed its Formula Products which contain BPA as superior, in terms of safety and supporting healthy development of infants and young children, and created a relationship with consumers based on trust and safety. As discussed further below, a major component of the manufacturing of the Contaminated Formula Products is the sterilization process, which exposes the formula in the epoxy-lined metal cans to intense heat. BPA leaching is accelerated by heat. Thus, the epoxy lining that Mead Johnson claims protects the formula from the metal cans during the manufacturing process is precisely what causes the BPA contamination.

2. BPA, a chemical that Mead Johnson uses to make its Contaminated Formula Products, is a dangerous chemical that has been linked to serious human health problems. Indeed, for an extended period of time, researchers and scientists have been very concerned with the harmful effects of BPA. For well over a decade, hundreds of studies and papers, including very recent reports, have repeatedly shown that BPA can be toxic to humans at extremely low doses. Recent studies using laboratory animals, human tissue, and human subjects have confirmed significant health risks associated with exposure to very low levels of BPA. Furthermore, research shows that infants and young children are especially susceptible to the dangers of BPA.

3. Incredibly, and despite these facts, Mead Johnson continued to market its Contaminated Formula Products as healthy and safe and failed to provide truthful or adequate warnings and/or information about BPA on its Contaminated Formula Products or their packaging. Indeed, Mead Johnson knew or should have known, but failed to disclose or adequately disclose the following material facts, *inter alia*: (1) that its Contaminated Formula Products contained BPA; (2) that numerous scientific studies performed by, among others, government scientists and university laboratories, had found health concerns associated with BPA; (3) that BPA leaching is accelerated by heat; and (4) that the industry studies provided to the United States Food and Drug Administration ("FDA") by chemical companies that manufacture BPA, and upon which Defendant relies in representing that BPA is safe, are flawed.

4. Moreover, Mead Johnson made these misrepresentations and failed to disclose these material facts in the context of a relationship of trust, which it likewise deceptively promoted.

5. Thus, while Mead Johnson pursued its strategy of marketing its Contaminated Formula Products to new parents, caregivers and other consumers as safe, its marketing of its Contaminated Formula Products concealed and/or omitted information that was material to consumers' purchasing decisions. In addition, Defendant's marketing has been false and deceptive in claiming its Contaminated Formula Products were safe and healthful. The goal of Defendant's scheme was and remains clear – to keep parents and consumers ignorant of the potential dangers of BPA exposure and to reap significant financial rewards through this unlawful conduct to the detriment of Plaintiffs and the Class. In fact, through this fraudulent and deceptive scheme, Mead Johnson reaped millions of dollars in profits that it otherwise would not

have obtained and caused Plaintiffs and Class members to expend money on products that they would not have purchased had they known the truth.

II. PARTIES

6. Plaintiff Dale L. Raggio, Jr. is a resident of the State of Arizona. He purchased Contaminated Formula Products containing BPA and bearing the mark of Defendant during the relevant time period.

7. Plaintiff Anne Beckner is a resident of the State of California. She purchased Contaminated Formula Products containing BPA and bearing the mark of Defendant during the relevant time period.

8. Plaintiff Matthew Spring is a resident of the State of California. He purchased Contaminated Formula Products containing BPA and bearing the mark of Defendant during the relevant time period.

9. Plaintiff Robin Anderson is a resident of the State of California. She purchased Contaminated Formula Products containing BPA and bearing the mark of Defendant during the relevant time period.

10. Plaintiff Leeanne Matusek is a resident of the State of California. She purchased Contaminated Formula Products containing BPA and bearing the mark of Defendant during the relevant time period.

11. Defendant Mead Johnson is a Delaware corporation, incorporated in August 2008, and a wholly-owned subsidiary of Bristol-Myers Squibb Company, a global biopharmaceutical and related health care products company. Mead Johnson's global headquarters are at 2400 West Lloyd Expressway, Evansville, Indiana, U.S.A. 47721. Mead Johnson develops, manufactures, markets, distributes, and sells Contaminated Formula Products, including products marketed under the brand name Enfamil.™ Mead Johnson has conducted and continues to

conduct business in Indiana and nationwide by distributing and selling its Contaminated Formula Products through various stores and supermarkets located throughout Indiana and the United States of America.

12. Despite Mead Johnson's nationwide sale of its Contaminated Formula Products, the most significant relationship between Mead Johnson on the one hand, and Plaintiffs and the Class on the other, occurs in Indiana, the center of Mead Johnson's wrongful conduct. As noted above, Mead Johnson's corporate headquarters are located in Evansville, Indiana, where significant executive decisions are made, including the decision to sell Contaminated Formula Products containing BPA. Mead Johnson's corporate officers, including Stephen W. Golsby, Chief Executive Officer and Director, Peter G. Leemputte, Senior Vice President and Chief Financial Officer, Lynn H. Clark, Senior Vice President, Human Resources, Stanley D. Burhans, Vice President and Controller, James M. Cornelius, Chairman of the Board of Directors, and Lamberto Andreotti, Vice Chairman of the Board of Directors, are located in Evansville, Indiana.

III. JURISDICTION AND VENUE

13. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1332. The Class includes more than 100 individuals. Members of the Class are citizens of a state different from Defendant, and the amount of controversy, in the aggregate, exceeds the sum of $5,000,000.00, exclusive of interest and costs.

14. Venue in this Court is proper pursuant to 28 U.S.C. §1391(a) because a substantial part of the events and/or omissions giving rise to the claims asserted herein occurred in this District, and Defendant is subject to personal jurisdiction in this District. Moreover, Defendant inhabits and/or may be found in this District and the interstate trade and commerce described herein is and has been carried out in part within this District.

IV. APPLICATION OF INDIANA LAW

15. Indiana law applies to the claims and issues asserted herein. Plaintiff seeks damages and equitable relief on behalf of himself and all other United States residents similarly situated, including residents of Indiana, under the laws of the State of Indiana.

16. All of Defendant's relevant business, including the formulation and execution of the unlawful practices alleged herein, occurred in, or emanated from Evansville, Indiana, where Defendant has its headquarters and principal place of business. Defendant also maintains its liquid manufacturing and packaging facilities in Evansville, Indiana, from where its liquid products are distributed throughout the United States. Morevoer, Defendant's customer service department regarding its pediatric products is located in Indiana.

17. Defendant's laboratories, including its $26.2 million Global Research and Development Technology Center, are also located in Evansville, Indiana. According to Defendant's CEO, the technology center positions the company for continued advancement of its leadership position in the global pediatric nutrition marketplace while also benefitting Evansville and Southwestern Indiana by linking investment in biosciences with economic growth. Accordingly, Indiana has significant contacts and/or a significant aggregation of contacts to the claims asserted by Plaintiff and all proposed Class members.

18. Indiana has a materially greater interest than any other State in regulating unlawful conduct by Defendant, which conducted its unlawful practices out of its operations and principal place of business in Indiana, and in enforcing the rights and remedies granted to United States consumers, including Indiana residents, under the Indiana laws invoked by this Complaint. These rights and remedies further strong fundamental public policies of the State of Indiana.

V. FACTUAL ALLEGATIONS

A. The Baby Formula Industry

19. Baby formula is a synthetic version of mothers' milk and belongs to a class of materials known as dairy substitutes, which are made by blending fats, proteins, and carbohydrates using the same technology and equipment used to manufacture dairy products. Until the early 1990s, formula was sold as a pharmaceutical product. Salespeople presented their brands to pediatricians, who would then recommend the products to new mothers. In 1992, federal antitrust actions resulted in the manufacturers shifting to directly market their products to consumers. Now, in addition to pharmaceutical sales, manufacturers' marketing strategies rely heavily on direct mail campaigns as well as television and print advertising.

20. Historically, the U.S. infant formula industry has been comprised of a small number of manufacturers with many of those manufacturers being owned by pharmaceutical companies. In 1987, three manufacturers, all owned by pharmaceutical companies, accounted for 99 percent of the total U.S. market share of infant formula: Ross Labs, owned by Abbott Laboratories; Mead Johnson, owned by Bristol-Myers; and Wyeth-Ayerst Laboratories, owned by American Home Products. Since 1987, several other companies have joined the U.S. infant formula market: Nestle, which owns infant formula manufacturers Carnation and Gerber; PBM Products; and a number of organic companies that are looking to break into the infant formula market.

21. The manufacturing process for infant Contaminated Formula Products involves multiple steps and facilitates leaching of BPA into the infant formula during the packaging process. *See* Randy Schueller, "Baby Formula: How Products are Made" Volume 4 (1996), available at *http://findarticles.com/p/articles/mi_gx5205/is_/ai_n19124707?tag=artBody;co11* at 3. The ingredients of infant formula are mixed together, pasteurized, homogenized, subjected to

a standardization process to ensure that key parameters such as pH, fat concentration, and vitamin and mineral are correct, and then packaged. The packaging process generally involves pouring liquid formula into metal cans lined with BPA, using conventional liquid filling equipment commonly used in the food and beverage industry, after which the lids of the metal cans are crimped into place. After the formula is placed into the cans and the cans are sealed, there is an additional sterilization of the formula-filled metal cans by subjection to heat and cold to destroy any additional microorganisms. The finished cans are packed in cartons and stored for shipping.

B. Bisphenol A, Its Uses, and Human Exposure.

22. As discussed above, this action concerns BPA, the toxic material used in Contaminated Formula Products produced, manufactured, distributed, and/or sold by Defendant. BPA is a component of epoxy resins widely used in consumer products, including can liners like those produced, manufactured, distributed, and/or sold by Defendant. BPA is a synthetic estrogen known as "xenoestrogen" and acts as an endocrine disruptor.[1]

23. The durability of the epoxy lining derives from its polycarbonate composition. Polycarbonate is a tough thermoplastic that is clear, lightweight and shatter-resistant. Consequently, these attributes have made polycarbonate the material of choice for a diverse range of products. However, the chemical bond between BPA molecules is unstable and, with time and use, the chemical leaches into materials it comes into contact with (for example, formula).[2] With respect to infant formula products produced by Defendant, liquid formulas and

[1] Erickson, Britt (June 2, 2008). "Bisphenol A under scrutiny". *Chemical and Engineering News* 86 (22): 36-39, *available at* http://pubs.acs.org/cen/government/86/8622gov1.html.

[2] *See* "Baby's Toxic Bottle", The Work Group for Safe Markets, at 6, available at http://chej.org/documents/BabysToxicBottleFinal.pdf.

other food products sold in metal cans are lined with BPA-epoxy, which has been shown to leach into the formula itself.

24. Although the epoxy resin containing BPA appears safe, it is actually dangerously flawed in a manner undetectable to the human eye. The chemical bond that links BPA monomers to one another to form polymer chains is not stable; as a result, the polymers decay with time allowing BPA to "leach" invisibly from polycarbonate plastic containers and metal cans lined with epoxy resins containing BPA.[3] When liquid or food comes into contact with the decayed area of a BPA epoxy resin can liner or polycarbonate plastic food container, BPA is released into the liquid or food in the container and subsequently ingested by the user. This leaching of BPA into liquid or food is accelerated and exacerbated by heat; thus, when the Contaminated Formula Products are subjected to heat, — *e.g.* during the manufacturing and/or shipping process — the dangers associated with BPA exposure are heightened.

25. According to the National Alliance for Breastfeeding Advocacy, BPA resins used as lacquers to coat metal products such as food cans have been shown to leach into the content of cans during the sterilization process, including cans of milk-based infant formula. *See* Walker, Marsha; RN. "Contaminants In Infant Formula." International Board of Lactation Consultant Examiners (available at *http://www.naba-breastfeeding.org/images/Contaminants.pdf*) 2002. Thus, BPA leaches during the manufacturing process into the liquid formula itself.

26. A number of studies report that BPA definitely leaches into formula from the lining of the metal can in which it is packaged. One such study was published on December 5, 2007, by the Environmental Working Group ("EWG"), an independent non-profit research

[3] A monomer is a small molecule that may become chemically bonded to other monomers to form a polymer. A polymer is a substance composed of molecules with large molecular mass consisting of repeating structural units, or monomers, connected by covalent chemical bonds. The individual molecules that comprise a polymer are referred to as polymer molecules. In popular usage, the term "polymer" is used as a synonym for plastic.

organization. In a test of six liquid formula samples, the EWG found an average of 5.3 parts per billion (ppb) of BPA in the infant formula, with a maximum of 17 ppb in some of the samples.[4] In addition to its own sampling, the EWG used baby formula sampling from a 1997 FDA study on BPA exposure in infant formula.[5] The 1997 study tested 14 liquid formula samples and found similar amounts of BPA with an average of 5 ppb and a maximum of 13 ppb.[6] The BPA ranges found in infant formula show a concentration at which concluded that infants fed the formula would be exposed to BPA at doses exceeding those that caused harm in laboratory studies.

27. The U.S. government recognizes key facts related to risks of harm from BPA. The National Toxicology Program ("NTP") noted, among other things, (i) that the primary source of exposure to BPA for most people is through the diet, in food and beverages; (ii) that BPA can migrate into food from food and beverage containers with internal epoxy resin coatings; and (iii) that the highest estimated intakes of BPA in the general population occur in infants and children. Infants and children have higher intakes of BPA because they eat, drink, and breathe more than adults on a pound-for-pound basis. Moreover, the toxic levels are of particular concern because of infants' inability to efficiently metabolize BPA.

28. The NTP also noted that bio-monitoring studies show that human exposure to BPA is widespread. The 2003 – 2004 National Health and Nutrition Examination Survey ("NHANES III") conducted by the Centers for Disease Control and Prevention ("CDC") found detectable levels of BPA in 93% of 2,517 urine samples from people six years and older. *See*

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[4] *Guide to Infant Formula and Baby Bottles*, EWG (available at: http://www.ewg.org/book/export/html/25570)

[5] *See* Biles, J.A., T.P. McNeal, T.H. Begley and H.C. Hollifield, 1997, *Journal of Agricultural and Food Chemistry*, vol. 45.

[6] *See* EWG's Guide to Infant Formula and Baby Bottles: BPA in baby bottles, *available at* http://www.ewg.org/node/25572 (citing EWG. 2007a. Toxic Plastics Chemical in Infant Formula. Environmental Working Group, Washington DC, a*vailable at*: http://www.ewg.org/reports/bpaformula [accessed 2007].) (citing Biles JE, McNeal TP, Begley TH. 1997. FDA-Determination of bisphenol A migrating from epoxy can coatings to infant formula liquid concentrates. J Agric Food Chem 45: 4697-700.).

National Institute of Environmental Health Sciences, Since You Asked – Bisphenol A, *http://www.niehs.nih.gov/news/media/questions/sya-bpa.cfm* (last visited Dec. 23, 2008). Almost all human exposure to BPA is through diet; with infants among the most exposed.[7]

29. The NHANES III study also revealed that females had statistically higher BPA levels than males, and children had higher concentrations than adolescents who, in turn, had higher concentrations than adults.[8]

30. Although this study did not include children younger than six years of age (the most affected demographic), the CDC NHANES III data showing increased exposure to women and children are considered representative of exposures in the United States because of the large number of people included in the survey and the process used to select participants.

(1) Numerous Studies Have Associated BPA Exposure with Negative Health Effects

31. For well over a decade, scientists have been concerned about the harmful effects of BPA on human health. Over 100 scientific studies have demonstrated the toxicity of BPA, even at extremely low doses, and studies of humans and lab animals have confirmed significant health risks associated with exposure to BPA.

32. Frederick vom Saal, a leading BPA researcher, realized the effects of BPA at low doses over a decade ago.[9] His early studies found that doses 25,000 times below the level considered safe by the government in fact harmed developing cells in mice. Upon publication of his work, representatives of BPA manufacturers ("the industry") encouraged him to delay further

[7] "Draft Brief on Bisphenol A", National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health, U.S. Department of Health and Human Services (April 14, 2008), at 4 , available at http://cerhr.niehs.nih.gov/chemicals/bisphenol/BPADraftBriefVF_04_14_08.pdf.

[8] BPA exposure among pregnant women also results in exposure to the fetus. *See* Takahashi, O., et al., *Disposition of Orally Administered 2,2-Bis (4-hydroxyphenyl) propane (Bisphenol A) in Pregnant Rats and the Placental Transfer to Fetuses*, Environmental Health Perspectives 108: 931-935.

publication of the actual dangers associated with BPA at everyday exposure levels. Vom Saal declined and has become a leading voice setting forth the deleterious effects of BPA at low doses, as well as the ways in which industry studies have obscured these facts.

33. A flood of information about BPA revealing both widespread human exposure and negative effects at even extremely low doses sparked a call for a new risk assessment of the compound.[10] Studies have concluded that exposure to very low levels of BPA can cause changes in brain structure and behavior,[11] and that BPA exposure adversely affects prostate development[12] and causes precancerous prostate lesions.[13] At very low levels of exposure, research indicates that BPA stimulates androgen-independent (*i.e.*, therapy-resistant) proliferation of prostate cancer cells,[14] increases the potency of prostate tumors,[15] speeds the pace of sexual development and causes obesity,[16] impacts estrous cyclicity and plasma LH levels,[17] lowers sperm count in adult males,[18] and creates "superfemale" attributes.[19] Several

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[9] *See* Lyndsey Layton, *Studies on Chemical In Plastics Questioned*, Wash. Post, Apr. 27, 2008, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2008/04/26/AR2008042602126_pf.html

[10] *See* vom Saal, F., et al., *An Extensive New Literature Concerning Low-Dose Effects of Bisphenol A Shows the Need for a New Risk Assessment*, Environmental Health Perspectives 115:8 (August 2005).

[11] *See* Kubo, K., et al., *Low dose effects of bisphenol A on sexual differentiation of the brain and behavior in rats*, Neuroscience Research 45: 345-356.

[12] *See* Timms, B. G., et al., *Estrogenic chemicals in plastic and oral contraceptives disrupt development of the fetal mouse prostate and urethra*, Proceedings of the National Academy of Sciences, 10.1073/pnas.0502544102.

[13] *See* Ho, S-M, et al., *Developmental Exposure to Estradiol and Bisphenol A Increases Susceptibility to Prostate Carcinogenesis and Epigenetically Regulates Phosphodiesterase Type 4 Variant 4*, Cancer Research 66: 5624-5632.

[14] *See* Wetherill, Y. B., et al., *The Xenoestrogen Bisphenol A Induces Inappropriate Androgen Receptor Activation and Mitogenesis in Prostatic Adenocarcinoma Cells*, Molecular Cancer Therapeutics 1: 515-524.

[15] *See* Ramos, JG, et al., *Prenatal Exposure to Low Doses of Bisphenol A Alters the Periductal Stroma and Glandular Cell Function in the Rat Ventral Prostate*, Biology of Reproduction 65: 1271-1277. speeds the pace of sexual development and causes obesity,

[16] *See* Hodeshell, K., et al., *Plastic bisphenol A speeds growth and puberty*, Nature 401: 762-764.

[17] See Rubin, B. S., et al., Perinatal Exposure to Low Doses of Bisphenol A Affects Body Weight, Patterns of Estrous Cyclicity, and Plasma LH Levels, Environmental Health Perspectives 109: 675-680.

[18] *See* Sakaue, M., et al., *Bisphenol-A Affects Spermatogenesis in the Adult Rat Even at a Low Dose*, Journal of Occupational Health 43: 185-190.

weak estrogenic compounds including BPA are ***as powerful as estrogen*** at increasing calcium influx into cells and stimulating prolactin secretion.

34. BPA has been detected in human follicular fluid, human amniotic fluid, and human breast milk, which clearly demonstrates prenatal, fetal, and neonatal exposure to BPA in humans.[20] Experiments with rats and mice have long demonstrated that low-level BPA exposure during fetal growth is linked to breast cancer[21] and increases the risk for other cancers in adults, affecting mammary tissue development[22] and increasing the presence of a chemical known to cause breast cancer.[23]

35. BPA is considered an "endocrine disruptor" and causes a response in cells similar to the effect of estradiol (an estrogen hormone). BPA binds with estrogen-related receptors without replacing the activity of estrogen. As a result, BPA adds a "false" estrogen effect in the body and off-sets the hormonal balance required for healthy human development.

36. Studies show that low doses of BPA can disrupt other types of hormone action within cells, such as thyroid hormone. BPA has been reported to suppress the activation of thyroid hormone-regulated genes in rats and competitively displace naturally occurring thyroid

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[19] *See* Oehlmann, J., et al., *Effects of endocrine disruptors on Prosobranch snails (Mollusca:Gastropoda) in the laboratory. Part I: Bisphenol A and Octylphenol as Xenoestrogens*, Exotoxicology 9: 383-397.

[20] Ikezuki Y, et al. *Determination of bisphenol A concentrations in human biological fluids reveals significant early prenatal exposure*. Hum Reprod. 2002 Nov; 17(11):2839-41. Schönfelder G et al. *Parent bisphenol A accumulation in the human maternal-fetal-placental unit*. Environ Health Perspect. 2002 Nov;110(11):A703-7. Kuruto-Niwa R, et al. *Measurement of bisphenol A concentrations in human colostrum.* Chemosphere. 2007 66(6):1160-4. Ye X, et al. *Measuring environmental phenols and chlorinated organic chemicals in breast milk using automated on-line column-switching-high performance liquid chromatography-isotope dilution tandem mass spectrometry*. J Chromatogr B Analyt Technol Biomed Life Sci. 2006 Feb 2;831(1-2):110-5.

[21] *See* Murray, T. J., et al., *Induction of mammary gland ductal hyperplasias and carcinoma in situ following fetal bisphenol A exposure*, Reproductive Toxicology 23: 383-390.

[22] *See* Markey, C. M., et al., *In Utero Exposure to Bisphenol A Alters the Development and Tissue Organization of the Mouse Mammary Gland*, Biology of Reproduction 65: 1215-1223.

[23] *See* Durando, M., et al. *Prenatal Bisphenol A Exposure Induces Preneoplastic Lesions in the Mammary Gland in Wistar Rats*, Environmental Health Perspectives 115, No. 1 (January 2007).

hormones. These hormones regulate the rate of metabolism and the growth of many systems in the body. Thyroid hormones play a significant role in brain development during fetal life.

37. Studies show that BPA can alter the expression of several hundred genes with effects varying among specific tissues and depending upon the timing of exposure.[24]

38. A recent review of scientific literature affirms that BPA can alter brain chemistry and the reproductive and immune systems in a variety of animals.[25] Some research also indicates that the sexual behavior and sexual development of mice can be impaired and variably altered from BPA-induced hormone disruption.[26] Another study found that female mice exposed to short-term, low doses of BPA experienced sudden and significant increases in genetic abnormalities in their eggs.[27]

39. In addition, chronic adult exposure to BPA causes insulin resistance.[28] BPA levels are higher in women with a history of repeated spontaneous miscarriages[29] and BPA is known to cause aneuploidy, an underlying cause of spontaneous miscarriages and birth defects.[30] Exposures to BPA at very low levels, well below the level previously considered safe, are sufficient to promote fat cell (adipocyte) differentiation and accumulation of lipids in a cell

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[24] *See* Rachel Gibson, "Toxic Baby Bottles: Scientific study finds leaching chemicals in clear plastic baby bottles", at 4, Environment California Research & Policy Center, 2007.

[25] vom Saal, F. and Hughes, C.. 2005. An extensive new literature concerning low dose effects of bisphenol shows the need for a new risk assessment. *Environmental Health Perspectives* 113(8): 926-933.

[26] Rubin B.S., Lenkowski J.R., Schaeberle, C.M., Vandenberg. L.N., Ronsheim. P.M., Soto. A.M. 2006. Evidence of altered brain sexual differentiation in mice exposed perinatally to low environmentally relevant levels of bisphenol A. *Endocrinology* 147:3681-3691.

[27] Hunt, P., et al. 2003. Bisphenol A exposure causes meiotic aneuploidy in the female mouse. *Current Biology* 13(7): 546-553.

[28] *See* Alonso-Magdalena, P., et al., *The Estrogenic Effect of Bisphenol-A Disrupts the Pancreatic B-Cell Function in vivo and Induces Insulin Resistance*, Environmental Health Perspectives 114:106-112.

[29] *See* Sugiura-Ogasawara, M., et al., *Exposure to bisphenol A is associated with recurrent miscarriage*, Human Reproduction 20: 2325-2329, August 2005.

culture line used as a model for adipocyte formation which cause human obesity,[31] and altered maternal behavior.[32]

40. Moreover, metabolic differences between rats and humans suggest humans may be ***more sensitive*** to BPA than rats.[33]

41. In addition, experiments "suggest[] that, following chemical damage, BPA continues to leach from polycarbonate even in the absence of further harsh treatment." [34]

42. In November, 2006, a group funded by the National Institute of Health ("NIH") and comprised of 38 of the world's leading scientists with regard to BPA (the "Group"), met at Chapel Hill, North Carolina to examine the relationship between BPA and the negative trends in human health that have occurred in recent decades, such as increases in abnormal penile/urethra development in males, early sexual maturation caused in females, increased neuron-behavioral problems such as ADD/HD and autism, increased childhood and adult obesity and Type II diabetes, regional decreases in sperm count, and an increase in hormonally mediated cancers, such as prostate and breast cancers. The Group gave heightened attention to the relationship between treatment with "low doses" of BPA and the many negative health outcomes confirmed by experimental studies in laboratory animals and in *in vitro* studies identifying plausible molecular mechanisms responsible for mediating such effects.

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[30] *See* Thomas, B. F., et al., *Bisphenol A exposure causes meiotic aneuploidy in the female mouse*, Current Biology 13: 546-553.

[31] *See* Masuno, H., et al., *Bisphenol A in combination with insulin can accelerate the conversion of 3T#-L1 fibroblasts to adipocytes*, Journal of Lipid Research 3:676-684.

[32] *See* Palanza, P., et al, *Exposure to a low dose of Bisphenol A during fetal life or in adulthood alters maternal behavior in mice*, Environmental Health Perspectives 110 (suppl 3): 415-422

[33] *See* Elsby, R., et al., *Comparison of the modulatory effects of human and rat liver microsomal metabolism on the estrogenicity of bisphenol A: implications for extrapolation to humans*, Journal of Pharmacology and Experimental Therapeutics 297-103-113.

[34] *See* Thomas, B. F., et al., *Bisphenol A exposure causes meiotic aneuploidy in the female mouse*, Current Biology 13: 546-553.

43. This eminent collection of scientists concluded that the wide range of adverse effects of low doses of BPA in laboratory animals exposed both during development and in adulthood "is a great cause for concern with regard to the potential for similar adverse effects in humans." The Group also concluded that recent trends in human diseases relate to adverse events observed in experimental animals exposed to low doses of BPA, the specific examples of which include many of the harmful conditions described above.

44. The Group found extensive evidence that negative health outcomes may not become apparent until long after developmental stage exposure to BPA has occurred. Furthermore, the Group's findings indicate that acute studies in animals, particularly traditional toxicological studies testing only high dose exposure to BPA, (like those relied upon by the chemical and plastic industries), do not accurately reflect exposure or effects in humans.

45. In addition, recent academic studies concerning BPA and its potential effects on human health continue to demonstrate that BPA exposure is potentially harmful to infants, children and adults in many ways.

46. A study on BPA's effects on human tissue funded and published by the National Institute of Environmental Health Sciences ("NIEHS"), a division of the NIH, released on August 14, 2008, found that BPA suppresses adiponectin, the hormone that regulates insulin sensitivity in the body, placing people at a substantially higher risk for metabolic syndrome.[35] The study was performed using human tissue harvested from "tummy tuck," or abdominoplasty, gastric bypass, and breast reduction surgical patients. These findings link BPA exposure to ongoing human health risks *i.e.*, dangers in addition to and beyond developmental abnormalities in children. Among other things, the researchers noted these results were relevant to

[35] Metabolic syndrome is a combination of risk factors that include lower responsiveness to insulin and higher blood levels of sugar and lipids (leading to high blood pressure, heart disease, diabetes, obesity, etc.).

consideration of the American obesity epidemic. *See* Hugo, Eric, et al., *Bisphenol A at Environmentally Relevant Doses Inhibits Adiponectin Release from Human Adipose Tissue Explants and Adipocytes ENVIRONMENTAL HEALTH PERSPECTIVES* (Aug. 14, 2008).

47. Research on primates has shown central nervous system dysfunction associated with BPA exposure ***within daily limits currently considered safe*** by the FDA and the United States Environmental Protection Agency ("EPA"). There, scientists administered continuous low-dose BPA to primates at the limit specified as safe for daily exposure by the EPA. Even at this relatively low exposure level, BPA caused significant neurological damage, eliminating entirely certain synaptic responses in the spine (*i.e.*, BPA eliminated the ability of nerves to communicate with each other in the central nervous system of primates). The scientists conducting the study noted the profound implications of BPA's ability to interfere with spine synapse formation and certain synaptic responses in the prefrontal cortex[36] and the hippocampus,[37] including that this remodeling of spine synapses may play a critical role in cognition and mood. This study, performed previously on rodents with consistent results, also suggests that the effect of BPA on rodents mimics closely the effects on primates, which are genetically closer to humans. Leranth, Csaba, et al., *Bisphenol A prevents the synaptogenic response to estradiol in hippocampus and prefrontal cortex of ovariectomized nonhuman primates, PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES* (Sept. 2, 2008) (*available at*, http://www.pnas.org/content/105/37/14187) (last visited Oct. 7, 2008).

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[36] The prefrontal cortex is the area of the brain linked with personality and "executive function," including planning complex cognitive behaviors, personality expression, and moderating correct social behavior. The basic activity of this brain region is considered to be orchestration of thoughts and actions in accordance with internal goals. The prefrontal cortex functions to determine a person's ability to differentiate among conflicting thoughts, determine good and bad, better and best, same and different, future consequences of current activities, working toward a defined goal, prediction of outcomes, expectation based on actions, and social "control" (the ability to suppress urges that could otherwise lead to socially-unacceptable outcomes).

[37] The hippocampus is part of the brain involved in formation, retention and consolidation of new memories, olfaction (sense of smell) and spatial coding/cognitive mapping (sense of direction).

48. On September 17, 2008, the Journal of the American Medical Association ("JAMA") published findings with respect to BPA exposure and the presence of BPA in adults, finding that BPA is associated with increased risk of certain diseases, including heart disease, diabetes, and liver problems. The scientists suggested these were effects of long-term, low-dose BPA exposure. Persons in the quarter of the population with the highest levels of BPA were more than twice as likely to be diagnosed with diabetes or heart disease, and were more likely to have elevated liver enzymes, which suggested stress to the liver.[38]

49. Beginning in November, 2007, Health Canada, a Canadian government agency, evaluated human and animal studies on BPA, as well as research on the manner by which BPA leaches from consumer products. Health Canada focused primarily on BPA's effect on newborns and infants up to 18 months of age and determined that the current safety margin ought to be wider. *See* CBS News, http://www.cbc.ca/news/background/health/bisphenol-a.html (last visited Dec. 23, 2008). In April 2008, officials for the Canadian health and environmental ministries officially declared BPA toxic and announced that a complete ban on manufacture of BPA-containing baby bottles would be introduced within the year. That ban became effective in October, 2008.

(2) Exposure to BPA is Especially Harmful to Babies

50. Of immediate and urgent concern is BPA's toxicity and its link to significant health problems and the risks of dangerous developmental, neural and reproductive health effects on infants and young children.

[38] Lang, Iain A., *et al., Association of Urinary Bisphenol A Concentration With Medical Disorders and Laboratory Abnormalities in Adults*, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, Vol. 300, No. 11, (Sept. 17, 2008).

51. Testing by EWG and by the Food and Drug Administration ("FDA") indicates that under normal use, liquid formula could expose an infant to substantial amounts of BPA.[39] An August 2007 investigation by EWG estimated that at BPA levels found in Ready-To-Use liquid formula, 1 of every 16 infants fed the formula would be exposed to BPA at doses exceeding those that caused harm in laboratory studies.[40]

52. The primary source of exposure to bisphenol A for most people is through the diet.[41] Given the fact that babies are small and typically consume Defendant's Ready-To-Use formula as their sole, or main, source of food, babies that consume the Contaminated Formula are being exposed to high amounts of BPA.

53. The NTP testing determined that young animals metabolize bisphenol A less efficiently than adult animals.[42] It is understood that neonatal rats have higher concentrations of BPA in their blood compared to older animals given an equal exposure.[43] A reduced ability or efficiency to metabolize BPA is generally predicted for human fetuses and infants as well.[44]

54. Children are especially vulnerable to BPA because endocrine disruptors affect how their bodies grow and develop.[45] Young children still have immature organ systems, high metabolic rates, relatively low body weight, and are going through rapid physical development; therefore, even low levels of repeated exposure may lead to adverse health effects.[46] An expert

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[39] http://www.ewg.org/reports/infantformula.

[40] "EWG's Guide to Infant Formula and Baby Bottles: BPA in formula--how harmful?" *available at* http://www.ewg.org/node/25574.

[41] *See* "Draft NTP Brief on Bisphenol A", at 4, National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health, U.S. Department of Health and Human Services, April 14, 2008.

[42] *See id*. at 5.

[43] *See id*. at 5.

[44] *See id.*

[45] *See* http://www.chej.org/documents/BabysToxicBottleFinal.pdf.

[46] *See* http://chej.org/documents/BabysToxicBottleFinal.pdf.

panel of the U.S. National Toxicology Program recently concluded that BPA exposure to fetuses and to children could impact their behavioral and neural systems.[47] Exposure to children is particularly worrisome as children have immature detoxification systems, not equivalent to adults', and they are at a delicate stage of development.[48]

55. While it is undisputed that children are particularly susceptible to the devastatingly harmful effects of endocrine disrupters like BPA, many of the problems associated with BPA exposure do not become obvious or recognizable until years after the exposure takes place. Thus, there can be an unknown number of years in the life of a child before he or she is actually or correctly diagnosed with a disorder, disease, or illness caused by BPA.

56. For these reasons, infants and children are particularly at risk from BPA exposure. BPA's adverse effects on a child's intellectual ability and growth, as well as the potential for exposure related disease(s), take years or even decades to detect or diagnose.

(3) U.S. Government Scientists Have Confirmed There Is "Some Concern" for Human Health Risks Among Infants and Children from BPA Exposure

57. In the last year, research published by the United States Government has raised new concerns about the effects of BPA exposure to fetuses, infants, and children. On April 14, 2008, the NTP's Center for the Evaluation of Risks to Human Reproduction ("CERHR"), a division of the U.S. Department of Health and Human Services ("HHS"), issued a draft brief indicating its agreement with a scientific expert panel on BPA that found that there was "some concern" for neural and behavioral effects in fetuses, infants, and children at current human exposures, based on effects in the prostate and mammary glands and early puberty in girls. *See*

[47] *See* http://www.gentlenurturing.com/gentle_nurturing_newsroom/bisphenol_a_in_your_home/second_major_canadian_drops_bpa.

Draft NTP Brief On Bisphenol A, published Apr. 14, 2008, National Toxicology Program, National Institutes of Health, U.S. Dep't of Health and Human Services, *available at*, http://cerhr.niebs.nih.gov/chemicals/bisphenol/BPADraftBriefVF_04_14_08.pdf (last visited Dec. 23, 2008).

58. Recently, on September 3, 2008, the NTP issued its final brief, which echoed the findings of the draft. *See NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A*, September 2008, NIH Publication No. 08–5994 (the "NTP Brief") *available at*, http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.pdf (last visited Dec. 23, 2008). The NTP Brief found that infants' and children's BPA exposure far exceeded that of adults, and that there was "some concern" for risks to human health. The NTP further stated that deleterious effects of BPA could extend beyond developmental and other systems related to estrogenic binding, and encouraged scientists to broaden their research in this area. NTP Brief at 21.

59. NTP observed that studies with laboratory rodents show that exposure to high dose levels of BPA during pregnancy and/or lactation can decrease survival rates, birth weight, and growth rates of offspring early in life, and delay the onset of puberty in males and females. "These 'high' dose effects of [BPA] are not considered scientifically controversial and provide *clear evidence* of adverse effects on development in laboratory animals." NTP Brief at 9.

60. NTP also observed that a variety of neural effects, behavior alterations, precancerous lesions in the prostate and mammary glands, altered prostate gland and urinary tract development, and early onset of puberty in females have been reported in laboratory rodents

[48] *See* "Baby's Toxic Bottle", The Work Group for Safe Markets, at 8, *available at* http://chej.org/documents/BabysToxicBottleFinal.pdf.

exposed during development to much lower doses of BPA – levels consistent with current levels of human exposure.

61. NTP concluded, in part, that current exposures to BPA are possibly high enough to cause concern:

> The 'high' dose effects of [BPA] in laboratory animals that provide clear evidence for adverse effects on development, *i.e.*, reduced survival, birth weight, and growth of offspring early in life, and delayed puberty in female rats and male rats and mice, are observed at levels of exposure that far exceed those encountered by humans. However, estimated exposures in pregnant women and fetuses, infants, and children are similar to levels of [BPA] associated with several 'low' dose laboratory animal findings of effects on the brain and behavior, prostate and mammary gland development, and early onset of puberty in females.

NTP Brief at 32.

C. The Governmental Response to BPA has been Based on Flawed Studies and the Process Has Been Riddled With Conflicts of Interest

62. Federal agencies, including the FDA and the EPA, have been slow to recognize this clear evidence of harm associated with BPA exposure even in low doses. In 1976, Congress passed the Toxic Substances Control Act, 15 U.S.C. §§2601 *et seq.* (1976), the first law in the country to regulate industrial chemicals. Without any effort to affirmatively establish its safety, BPA was "grandfathered in," presumed safe by the EPA without evaluation of specific evidence. In addition, the FDA designated BPA to be among food contact items "Generally Recognized As Safe."[49] FDA, Safety and Food Packaging,

[49] Generally Recognized As Safe ("GRAS") is a legal category set up by Congress under the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act. According to the FDA, GRAS substances are those for which use in food has a "proven" track record of safety based either on a history of use before 1958 or on published scientific evidence, and that need not be approved by the FDA prior to being used. FDA, GRAS: Time-Tested, and Trusted, Food Ingredients, http://www.fda.gov/fdac/features/2004/204_gras.html (last visited Dec. 23, 2008). The FDA classifies certain chemicals and natural substances that are food additives and food contact substances as GRAS but nowhere maintains a complete list of all GRAS food contact items. "Because the use of a GRAS substance is not subject to premarket review and approval by FDA, it is impracticable to list all substances that are used in food on the basis of the GRAS provision (21 C.F.R. §182.1). The use of a substance is GRAS because of

http://www.fda.gov/consumer/updates/foodpackaging081908.html (last visited Dec. 23, 2008).[50] The EPA has set daily limits for human exposure, within which it claims BPA exposure is safe; the EPA reference ("safe") dose for BPA is 50 ug/kg/day.[51]

63. Despite years of scientific research raising questions as to its safety, the FDA has not altered its position with respect to the safety of BPA at current levels of human exposure. On August 14, 2008, the FDA released a *Draft Assessment Of Bisphenol A For Use In Food Contact Applications*, and stated its preliminary conclusion that "an adequate margin of safety exists for BPA at current levels of exposure from food contact uses." This draft report contradicted and rejected the findings of more than 100 studies performed by government scientists and university laboratories that found health concerns associated with BPA.

64. However, the FDA's position was predicated upon flawed studies supplied by the Industry, which has a strong financial incentive in ensuring the longevity of this dangerous chemical. Indeed, the validity of the FDA's unwavering position with respect to BPA has also been questioned because the FDA has relied exclusively on industry studies although virtually all academic and government scientific research on the issue has called the validity of the industry's studies into question.

65. Moreover, the independence of subsequent government inquiries of BPA has also come into question. Specifically, in February, 2007, it was revealed that Sciences International ("SI"), the sole firm contracted by the FDA to perform a survey of studies relating to BPA toxicity and potential reproductive hazards associated with exposure, also had major BPA

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widespread knowledge among the community of qualified experts, not because of a listing or other administrative activity." FDA, Frequently Asked Questions About Gras, http://www.cfsan.fda.gov/~dms/grasguid.html#Q1 (last visited Dec. 23, 2008).

[50] *See also* http://www.fda.gov/fdac/features/2004/204_gras.html; 21 C.F.R. §186.1.

[51] U.S. EPA 1993. Bisphenol A, CASRN 80-05-7. Washington, DC:Integrated Risk Information System, U.S. Environmental Protection Agency (*available at*, http://www.epa.gov/iris/subst/0356.htm (last visited Oct. 7, 2008)).

manufacturers, including Dow Chemical and BASF, as corporate clients and was therefore faced with a serious, undisclosed conflict of interest in its evaluation and assessment of BPA. The House Oversight and Government Reform Committee launched an investigation of the conflict of interest policies of NIEHS, the NIH agency responsible for hiring the industry contractor SI to conduct the BPA review. Congressman Henry Waxman and Senator Barbara Boxer asked the Director of NIEHS, Dr. David Schwartz, to provide information on potential conflicts of interest involving SI.

66. Ultimately, the government suspended and later fired SI because of concerns over its conflicts of interest. However, the BPA advisory panel, on whose behalf SI evaluated and reported on BPA, continued using the draft expert panel report prepared by SI, despite concerns as to accuracy and bias raised by advocates and independent scientists. Upon review by Tufts University biologist Dr. Ana Soto, nearly 300 errors were discovered in the SI draft report relied upon to form government policy on BPA.

67. In response to a congressional inquiry from the Committee on Energy and Commerce, on February 25, 2008, the FDA admitted that its determination that current levels of BPA exposure pose no health risks was based on just two studies, both sponsored by the American Plastics Council, the trade group that represents BPA manufacturers (hereinafter, "the industry"), one of which remains unpublished.[52] These studies, discussed in FDA memoranda dated July 18, 2007 and July 24, 2007, consisted of the following: (i) *Two generation reproductive toxicity evaluation of Bisphenol A administered in feed to CD-1 Swiss mice*, sponsored by the American Plastics Council and submitted to the FDA in March, 2007 (unpublished and un-peer reviewed); and (ii) *Three generation reproductive toxicity evaluation*

[52] *See* February 25, 2008 Letter from Stephen R. Mason, FDA Acting Assistant Commissioner for Legislation, to Rep. John Dingell, Chairman House Energy and Commerce Committee.

of Bisphenol A in the feed to CD-1 (Sprague-Dawley) rats, sponsored by the American Plastics Council and submitted to the FDA in 2000 (published in *Toxological Sciences* in 2002). The published industry study was widely criticized by BPA experts for its fatal design flaws. The second industry study has not been made available to the public and has not been published in a peer-reviewed journal to date.

68. On October 29, 2008, the FDA Science Board Subcommittee on Bisphenol A released a scientific peer-review of the Draft Assessment prepared by the FDA reporting on Bisphenol A for use in food contact applications. The Science Board Subcommittee found several shortcomings in the FDA Draft Assessment. The Science Board Subcommittee criticized the FDA's failure to accurately estimate BPA contamination in infant formula, specifically with reference to its reliance on an inadequate number of samples and the FDA's use of mean values which masked the variability among samples. The Science Board Subcommittee also noted the FDA's failure to consider over 100 independent studies performed by academic and government research labs, each of which found harms associated with low-dose exposure to BPA.

69. With respect to the considerable scientific challenges the safety of BPA exposure at levels currently considered "safe," the Science Board Subcommittee stated in no uncertain terms that "[t]he draft FDA report does not articulate reasonable and appropriate scientific support for the criteria applied to select data for use in the assessment," *id*. at 4, and disagreed with the FDA's decision to exclude government and academic research not performed under the "good laboratory practices" standards developed specifically for industry (not academic) research.

70. In its report, the Science Board Subcommittee further affirmed the NTP's process and the research it considered, reiterating its conclusions that there is some concern associated

with the contamination of infants and children with BPA at current levels of exposure. The Science Board Subcommittee specifically referenced recent studies on primates and humans linking BPA exposure in primates and humans to brain development issues, heart disease, diabetes, and other disorders as research improperly excluded from the FDA's Draft Assessment. The Science Board Subcommittee further recognized that the "no effects" level of BPA exposure set by the FDA was not supported by the available science. The Subcommittee noted that the "weight-of-the-evidence ... provides scientific support for use of a point of departure substantially below (*i.e.*, at least one or more orders of magnitude lower than) the 5 mg/kg bw/day level selected in the draft FDA assessment." *Id*. at 4. Most importantly, the Science Board Subcommittee noted that the FDA had not used scientifically valid means to determine safety levels for BPA contamination, noting that there is "a sufficient scientific basis to conclude that the Margins of Safety defined by FDA as 'adequate' are, in fact, 'inadequate.'" *Id*. at 4. The full Science Board of the FDA unanimously approved its Subcommittee's recommendations with respect to these issues on October 31, 2008.

71. As recently as December 24, 2008, it was reported that the Science Board Subcommittee found, after receiving comments from an independent advisory panel, that the FDA should not have disregarded the numerous studies showing adverse health effects of BPA. As noted above, the FDA's position was based on two studies performed by research groups that received funding from the American Plastics Council. In this regard, Dr. Mitchell Cheeseman, deputy director of the agency's Office of Food Additive Safety, noted the significant flaws in the FDA's evaluation of the two studies used by the FDA in connection with BPA.

D. Mead Johnson's Wrongful Conduct.

72. Despite well-documented scientific evidence of the harmful effects of BPA on infants and children, Mead Johnson has made misrepresentations and/or omissions and failed to

disclose or adequately disclose that its Contaminated Formula Products are manufactured using a dangerous chemical recognized (and known to it) as toxic in several respects for years and which poses serious risks and harmful effects to individual health. Indeed, Mead Johnson often highlights the healthfulness of its Contaminated Formula Products.

73. By its own admission, Mead Johnson offered products containing BPA, including its popular infant formula, Enfamil. "Our cans for liquid products, including all 13 oz concentrate cans as well as all 8 fl oz and 32 fl oz ready-to-feed cans have an epoxy lining which contains a very low level of BPA." Mead Johnson, *http://www.meadjohnson.com/app/iwp/MJN/Content2.do?dm=mj&id=/MJN_Home2/mjnBtnNews/mjnBtnNewsArchive/08BPASafety&iwpst=B2C&ls=0&csred=1&r=3408044066* (Last visited Jan. 14, 2009). Mead Johnson's Contaminated Formula Products include but are not limited to:

a. Enfamil LIPIL Ready-to-Use Liquid Formula (32 fl oz and 8 fl oz cans)

b. Enfamil LIPIL Concentrated Liquid13 fl oz cans

c. Enfamil A.R. LIPIL Ready-to-Use Liquid Formula

d. Enfamil Nutramigen LIPIL Ready-to-Use Liquid Formula

e. Enfamil LactoFree LIPIL - 13 oz Concentrate Liquid

f. Enfamil LactoFree LIPIL - 32 oz Ready-to-Use

(1) Defendant's Deceptive Marketing of its Contaminated Formula Products

74. Despite lining its infant formula products with an epoxy lining that contains BPA, Mead Johnson failed to conduct any testing on its finished formula products to determine the amount of BPA that was ultimately contained in the Contaminated Formula Products.[53]

[53] *See* Response letter from Dirk Hondmann, Ph.D., Senior Vice President, Global Resarch & Development, Meade Johnson Nutritionals to Congressmen Dingell and Stupak, "Re: Committee on Energy and Commerce Questions

75. Mead Johnson's business and marketing strategy at all relevant times targets consumers who are, among others, new and/or expecting parents, by touting its Contaminated Formula Products as superior, in terms of both healthiness and safety, and by attempting to create a relationship based on trust and safety with its consumers. "We have 100 years of experience in integrating nutritional science with consumer marketing, allowing us to develop science-based clinically supported products that are precisely tailored to consumers' needs." Mead Johnson Form S-1 Registration Statement, filed with the Securities and Exchange Commission on December 18, 2008 (available at *http://idea.sec.gov/Archives/edgar/data/1452575/000119312508256053/ds1.htm*) (Last visited Jan. 14, 2009).

76. Indeed, Mead Johnson assured parents and other consumers of its Contaminated Formula Products' safety: "Mead Johnson Formulas Are Safe.…" Mead Johnson, *https://www.meadjohnson.com /app/iwp/HCP/guestHome.do?BV_UseBVCookie=yes&csred=1&r=3408045236*. Mead Johnson marketed its core commitment to safety even after a wealth of scientific research belied its claims. "As we develop our formulas, we strive for the best possible packaging and we are very confident of the safety of our current packaging." Mead Johnson, *http://www.meadjohnson.com/app/iwp/MJN/Content2.do?dm=mj&id=/MJN_Home2/mjnBtnNews/mjnBtnNewsArchive/08BPASafety&iwpst=B2C&ls=0&csred=1&r=3408044066* (last visited Dec. 29, 2008).

77. Mead Johnson's packaging similarly touts the healthfulness of its Contaminated Formula Products, noting its particular ability to mimic and achieve many of the health and safety benchmarks of natural breastfeeding. "Our blend of DHA and ARA for your baby's development. Whole proteins similar to breast milk. Plus balanced nutrition. No matter who you

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dated January 17, 2008", 2 (January 31, 2008) (stating ""We do not test our finished products for BPA … We therefore do not conduct additional testing of the contents of the cans for BPA").

need to nourish, Enfamil products have the nutrition you can depend on." Mead Johnson, *https://www.meadjohnson.com/app/iwp/HCP/guestHome.do?BV_UseBVCookie=yes&csred=1&r=3408045236* (last visited Dec. 29, 2008). Mead Johnson also emphasizes its Contaminated Formula Products' superiority. "Our Mission is to create nutritional brands and products trusted to give infants and children the best start in life." Mead Johnson, *https://www.meadjohnson.com/app/iwp/enfamil/enfHome.do?dm=mj&ls=0&csred=1&r=3408120385* (last visited Dec. 30, 2008). Mead Johnson specifically markets its Contaminated Formula Products to parents and consumers it knows, or should know, are particularly sensitive to health concerns and would not knowingly buy Contaminated Formula Products that place their children at risk for developmental, neural, and reproductive problems. However, the potentially devastating effects of BPA on infants and children are not mentioned or disclosed anywhere on such packaging.

78. While heralding its independent research and commitment to healthful product development, Mead Johnson misled consumers, self-admittedly taking advantage of its acknowledged omnipresence, longevity and research capabilities, to suggest that Mead Johnson's status in this regard would serve to greater inform consumer safety, rather than hide, problems with Mead Johnson's products.

> The Mead Johnson name has been associated with science-based pediatric nutrition products for 100 years.… Total unaided awareness of Enfamil® exceeded 90% in the United States in 2007. We believe we also own some of the most well-known regional and local brands in the industry …. We invest heavily in research and development to maintain our standing as one of the industry leaders in new product innovation…. We believe our global research and development capabilities, together with the strength of our brands and our ability to convert advances in nutritional science into marketable products, will continue to allow us to develop new products and improve existing products across each of our product categories.

Mead Johnson Form S-1 Registration Statement, filed with the Securities and Exchange Commission on December 18, 2008 (available at *http://idea.sec.gov/Archives/edgar/data/1452575/000119312508256053/ds1.htm*).

79. Mead Johnson admittedly designed its marketing and its public statements to create a relationship of trust and safety with its consumers.

> We are committed to creating trusted nutritional brands and products which help improve the health and development of infants and children around the world and provide them with the best start in life. Our Enfa family of brands, including Enfamil® infant formula, is the world's leading brand franchise in pediatric nutrition.… We have 100 years of innovation experience, during which we have developed or improved many breakthrough or industry-defining products across each of our product categories. Our singular focus on pediatric nutrition and our implementation of a business model that integrates nutritional science with health care and consumer marketing expertise differentiates us from many of our competitors.

See Mead Johnson Nutrition Company Form S-1 Registration Statement, filed with the Securities and Exchange Commission on December 18, 2008 (available at http://idea.sec.gov/Archives/edgar/data/1452575/000119312508256053/ds1.htm).

80. In addition to making these representations, Mead Johnson acknowledged and marketed its heavy influence on parents and consumers in the infant formula market in its statements to prospective investors in December, 2008: "We believe mothers and health care professionals associate the Mead Johnson name and the Enfa family of brands with quality, science-based pediatric nutrition products. We believe the strength of our brands allows us to create and maintain consumer loyalty across our product portfolio and stages of pediatric development." Mead Johnson Form S-1 Registration Statement, filed with the Securities and Exchange Commission on December 18, 2008 (available at http://idea.sec.gov/Archives/edgar/data/1452575/000119312508256053/ds1.htm).

81. To make matters worse, Mead Johnson continued to disregard the fact that BPA leaching is accelerated by heat and otherwise exacerbate the dangers of BPA exposure. Indeed, according to Dr. vom Saal, a leading expert on BPA, the fact that BPA would break down and leach out of the plastics under heat conditions is so self-evident that any college chemistry student examining BPA's molecular structure would easily understand that the molecule would break down under increased temperatures. Yet, on its website, Mead Johnson defends the use of Contaminated Formula Products and specifically invokes the very heat and sterilization conditions likely to accelerate the BPA leaching process:

> The [BPA] lining prevents elements in the metal from transferring to the formula, protects the potency of the nutrients and allows for safe product sterilization….***We are unaware of any alternative material that can withstand the sterilization process required for liquid infant formulas and provide the same assurance of product safety.***

Mead Johnson, http://www.meadjohnson.com/app/iwp/MJN/Content2.do?dm=mj&id=/ MJN_ Home2 mjnBtnNews/mjnBtnNewsArchive/08BPASafety&iwpst=B2C&ls=0&csred=1&r=*340804 4066* (last visited Dec. 29, 2008).

(2) Failure To Disclose

82. Despite the foregoing, including Defendant's representations that its Contaminated Formula Products are safe and designed to support healthy growth and development, Mead Johnson consistently failed to disclose or adequately disclose the dangers of BPA exposure to consumers. Significantly, Defendant was aware of, but failed to disclose or adequately disclose the following material facts, *inter alia*: (1) that its Contaminated Formula Products contained BPA; (2) that numerous scientific studies performed by, among others, government scientists and university laboratories, found health concerns associated with BPA; (3) that BPA leaching is accelerated by heat; and (4) that the industry studies that were provided

to the FDA by the chemical companies that manufacture BPA, and upon which Defendant relies in representing that BPA is safe, are flawed and were the result of a process that was riddled with conflicts of interest. Moreover, Defendant made its misrepresentations and failed to disclose these material facts in the context of a relationship of trust, which it likewise deceptively promoted.

83. Incredibly, Defendant nowhere mentions or discloses the danger of BPA exposure. Nor does it include warnings or information about BPA on its Contaminated Formula Products or the packaging. The goal of Defendant's conduct is clear – to keep parents and consumers ignorant of the potential dangers of BPA exposure. Even after public outcry over the risks of BPA exposure, Mead Johnson assuaged consumers' concerns with further reference to its "commitment" to safety: "our confidence in the quality and safety of our products is not changed." *Mead Johnson Statement on the Safety of BPA,* Mead Johnson, *http://www.meadjohnson.com/app/iwp/MJN/Content2.do?dm=mj&id=/MJN_Home2/mjnBtnNews/mjnBtnNewsArchive/08BPASafety&iwpst=B2C&ls=0&csred=1&r=3408044066* (last visited Dec. 29, 2008). Indeed, while Mead Johnson pursued its strategy of marketing its Contaminated Formula Products to new parents, caregivers and other consumers, it was aware that its advertising concealed information that was material to consumers' purchasing decisions. In addition, Mead Johnson knew that its marketing was false and deceptive in claiming its Contaminated Formula Products were safe and healthful.

84. Even today, despite the numerous studies (described above) to the contrary, Mead Johnson continues to claim that there are no credible scientific studies that demonstrate that BPA leaches from its Contaminated Formula Products. In fact, Mead Johnson publishes a section on its website entitled "Mead Johnson Statement on the Safety of BPA," where it continues to

maintain that "we are very confident of the safety of our current packaging." Mead Johnson *http://www.meadjohnson.com/app/iwp/MJN/Content2.do?dm=mj&id=/MJN_Home2/mjnBtnNews/mjnBtnNewsArchive/08BPASafety&iwpst=B2C&ls=0&csred=1&r=*3408044066 (last visited Dec. 30, 2008). Mead Johnson reassures parents and other consumers while failing to disclose the harms associated with use of its products. "You can be assured our products are safe.…" Mead Johnson, *http://www.meadjohnson.com/app/iwp /MJN/Content2.do?dm=mj&id=/MJN_Home2/mjnBtnNews/mjnBtnNewsArchive/08BPASafety&iwpst=B2C&ls=0&csred=1&r=*3408044066 (last visited Dec. 30, 2008). Furthermore, Mead Johnson publishes a statement on its website indicating it is aware of "recent media stories" concerning the use of BPA in plastic baby bottles:

> We are confident in the safety of our current packaging materials but we also understand that you may have questions about them given recent media stories about BPA. To help eliminate any concerns that you may have, we are working with suppliers of packaging components to review alternative new materials and processes. You have our commitment that the benefits and safety data of any new packaging material will be carefully weighed and that they will continue to insure the safety and nutritional quality that you expect from the Enfamil Family of Formulas™.

Mead Johnson, http://www.enfamil.com/app/iwp/MJN/Content2.do?dm=enf&id=/MJN_Home2/mjnBynNews/mjnnewsrchive/08BPAsafety&iw[st=MJN&is-o&csred_1&r=3409421722 (last visited Jan. 14, 2009). Mead Johnson nevertheless goes on to express the much-discredited belief that the weight of scientific evidence ensures the safety of this material for food contact applications. Mead Johnson, *http://www.Mead Johnson.com/bottles/FAQ.shtm* (last visited Dec. 17, 2008). Mead Johnson has possessed full knowledge of the studies and reports suggesting the potentially devastating risks of BPA discussed above.

85. Despite Mead Johnson's claims otherwise, there are viable alternatives for packaging its infant formula products that do not include BPA, as is evidenced by the fact that

there are liquid infant formula and other consumer products packaged in metal cans without the use of BPA. Mead Johnson has nevertheless continued to use the toxic chemical BPA in the vast majority of its Contaminated Formula Products. To increase profits, Defendant continues to manufacture and market these Contaminated Formula Products that contain BPA without full disclosure of their risks. Infant formula, a $13 billion industry, *see* Euromonitor. Market data for 2007, represented over 69% of Mead Johnson's $2.6 billion net sales for the year ending December, 31 2007. Mead Johnson Form S-1 Registration Statement, filed with the Securities and Exchange Commission on December 18, 2008 (available at *http://idea.sec.gov/Archives/edgar/data/1452575/000119312508256053/ds1.htm*). Indeed, Mead Johnson's position is consistent with its vested interest in ensuring that its share of profits derived from the continued manufacture and sale of BPA, which generates chemical industry revenues amounting to $6 million per day (in the U.S., Europe, and Japan alone), is not curtailed or reduced. Elvira Greiner, Thomas Kaolin and Coro Told, SRI Consulting, *Chemical Economics Handbook Report; Bisphenol A,* February 2001.

86. Having held itself out as a trustworthy source of safe and healthy baby formula products, Mead Johnson had a duty to disclose facts regarding the health risks that their Contaminated Formula Products posed, including that its Contaminated Formula Products contained BPA that would leach into food and beverages through the course of normal, everyday use, and the serious health risks posed by such BPA exposure. Mead Johnson has misrepresented and failed to disclose the risks of harm associated with its Contaminated Formula Products and has failed to make honest disclosures to Plaintiffs and other Class members. Plaintiffs and other Class members relied upon Mead Johnson's misrepresentations and lack of disclosure and have sustained injuries as a result thereof.

(3) Equitable Estoppel and Equitable Tolling of the Statute of Limitations

87. By virtue of its false statements, misrepresentations and omissions, Defendant actively misled the Class members concerning their legal rights and thus prevented the Class members from enforcing their legal rights.

88. Accordingly, Defendant should be estopped from relying upon any delay by the Class members in enforcing their rights under the law, if any, and all applicable statutes of limitations on the Class members' claims should be equitably tolled.

VI. CLASS ACTION ALLEGATIONS

89. Plaintiffs bring this class action claim pursuant to Rule 23 of the Federal Rules of Civil Procedure. The requirements of Rule 23 are met with respect to the classes defined below.

A. The Classes.

90. Plaintiffs brings their claim on their own behalf, and on behalf of the following classes:

> All persons in the United States who purchased Contaminated Formula Products containing the industrial chemical Bisphenol-A that were produced, manufactured, distributed, and/or sold by Defendant and who were accordingly damaged thereby, and/or such subclasses as the Court may deem appropriate.
>
> All persons who, in the Consumer Protection States,[54] purchased Contaminated Formula Products containing the industrial chemical Bisphenol-A that were produced, manufactured, distributed, and/or sold by Defendant and who were accordingly damaged thereby (the "Consumer Fraud Class"), and/or such subclasses as the Court may deem appropriate.

[54] The Consumer Protection States are defined hereinafter to include only the states of Alaska, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Vermont, Washington, West Virginia, Wisconsin, and Wyoming.

> All persons who, in the Non-Privity Breach of Express Warranty States,[55] purchased Contaminated Formula Products containing the industrial chemical Bisphenol-A that were produced, manufactured, distributed, and/or sold by Defendant and who were accordingly damaged thereby (the "Breach of Express Warranty Class"), and/or such subclasses as the Court may deem appropriate.
>
> All persons who, in the Non-Privity Breach of Implied Warranty States,[56] purchased Contaminated Formula Products containing the industrial chemical Bisphenol-A that were produced, manufactured, distributed, and/or sold by Defendant and who were accordingly damaged thereby (the "Breach of Implied Warranty Class"), and/or such subclasses as the Court may deem appropriate.

91. Plaintiffs reserve the right to amend or modify their Complaint and/or the Plaintiff Class definition in connection with meaningful discovery and/or a Motion for Class Certification.

92. Members of the Class are so numerous and geographically dispersed that joinder of all Class members is impracticable. The Class, upon information and belief, includes thousands if not hundreds of thousands of individuals geographically dispersed throughout the United States. The precise number and identities of Class members are unknown to Plaintiffs but can be easily obtained through notice and discovery. Indeed, notice can be provided through a variety of means including publication, the cost of which is properly imposed upon Defendant.

93. Plaintiffs will fairly and adequately protect the interests of all Class members and have retained counsel competent and experienced in class and consumer litigation.

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[55] The Non-Privity Breach of Express Warranty States are defined hereinafter to include only the states of Arkansas, Arizona, California, Colorado, Connecticut, District of Columbia, Hawaii, Indiana, Kansas, Louisiana, Maine, Massachusetts, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Washington, West Virginia, or Wyoming, which do not require privity.

[56] The Non-Privity Breach of Implied Warranty States are defined hereinafter to include only the states of Arkansas, Colorado, Delaware, District of Columbia, Hawaii, Indiana, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North

94. Plaintiffs' claims are typical of the claims of the Class and all Class members sustained uniform damages arising out of the conduct challenged in this action. The Class is ascertainable and there is a well-defined community of interests in the questions of law and/or fact alleged since the rights of each Class member were infringed or violated in a similar fashion based upon the Defendant's wrongdoing. The injuries sustained by the Plaintiffs and the Class members flow, in each instance, from a common nucleus of operative facts – the Defendant's wrongdoing. In every related case, Plaintiffs and Class members suffered uniform damages caused by their purchase of Contaminated Formula Products produced, manufactured, distributed, and/or sold by Defendant.

95. Defendant has acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the use of BPA in Defendant's Contaminated Formula Products.

96. In addition, there are questions of law and fact common to the Class that predominate over any questions solely affecting individual Class members. Defendant engaged in a common course of conduct giving rise to the legal rights sought to be enforced by Plaintiffs and the Class members. Individual questions, if any, pale by comparison to the numerous common questions that predominate. Such common questions include but are not limited to:

a. Whether Defendant represented to consumers that its Contaminated Formula Products were safe to use for their intended purpose or omitted material risks associated with the use of its Contaminated Formula Products;

b. Whether Indiana law applies to the nationwide class;

c. Whether Defendant violated applicable consumer protection statutes;

Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Texas, Utah, Virginia, West Virginia, or Wyoming, which do not require privity.

d. Whether Defendant violated express and/or implied warranties;

e. Whether Defendant negligently misrepresented or omitted characteristics of their Contaminated Formula Products;

f. Whether Defendant intentionally or fraudulently misrepresented or omitted characteristics of their Contaminated Formula Products;

g. Whether Defendant was unjustly enriched; and

h. Whether Plaintiffs and the Class were harmed and, if so, to what relief they are entitled.

97. A class action is superior to other available methods for the fair and efficient adjudication of this controversy because joinder of all Class members is impracticable. Furthermore, the expense and burden of individual litigation make it impossible for the Class members to individually redress the wrongs done to them.

VII. CAUSES OF ACTION

COUNT I: Violation of Indiana Deceptive Consumer Sales Act

98. Plaintiff incorporates by reference the preceding paragraphs as if they were fully set forth herein. Plaintiff brings this claim on behalf of himself and all other persons who purchased Contaminated Formula Products produced by Mead and marketed nationwide, asserting claims under the Indiana Deceptive Consumer Sales Act, IC 25-5-0.5, *et seq.* ("IDCSA").

99. The IDCSA broadly prohibits businesses from using deceptive and unconscionable sales practices.

100. Plaintiff is a "person" as defined by the IDSCA, IC 24-5-0.5-2(a)(2).

101. The sale of the Contaminated Formula Products by Defendant is a "consumer transaction" as defined by the IDSCA, IC 24-5-0.5-2(a)(1).

102. Defendant is a "supplier" defined by the IDSCA, IC 24-5-0.5-2(a)(3).

103. In the conduct of trade or commerce regarding its production, marketing, sale, and distribution of its Contaminated Formula Products, Defendant engaged in one or more deceptive or unconscionable sales practices, including but not limited to failing to disclose or adequately disclose the following material facts, *inter alia*: (1) that its Baby Products contained BPA; (2) that numerous scientific studies performed by, among others, government scientists and university laboratories, found health concerns associated with BPA; (3) that BPA leaching is accelerated by heat; and (4) that the industry studies that were provided to the FDA by the chemical companies that manufacture BPA, and upon which Defendant relies in representing that BPA is safe, are flawed.

104. By means of the conduct alleged in this Complaint, Defendant violated the IDSCA, in the production, marketing and sale of its Contaminated Formula Products. Defendant has made the following representations, among others, specifically prohibited as deceptive acts by the IDSCA:

> (1) That the subject of a consumer transaction has sponsorship, approval, performance, characteristics, accessories, uses, or benefits it does not have which the supplier knows or should reasonably know it does not have; and
>
> (2) That the subject of a consumer transaction is of a particular standard, quality, grade, style, or model, if it is not and if the supplier knows or should reasonably know that it is not.

105. By producing, marketing, selling, and distributing its Contaminated Formula Products in containers lined with polycarbonate plastic containing BPA Defendant either knew, recklessly disregarded or reasonably should have known that its products imposed significant health risks, Plaintiff is informed and believes and based thereon alleges that Defendant reaped

millions of dollars in profits that it otherwise would not have obtained and caused Plaintiff and the Class members to expend money on products which were unsafe.

106. Defendant's wrongful conduct emanated, and continues to emanate, from Indiana. Specifically, Mead is headquartered in Indiana and its executives are located in Indiana. In addition, many of the Contaminated Formula Products were purchased in stores and on websites located in Indiana. Further, Mead should have known and expected that its trade practices would be subject to the IDSCA given that the bulk of the circumstances surrounding the fraudulent transactions occurred primarily and substantially in Indiana. Thus, application of the IDSCA on a nationwide basis to Mead's conduct is entirely appropriate.

107. Plaintiff is informed and believes and based thereon alleges that Defendant engaged in its unfair and unconscionable conduct for the purpose of obtaining millions of dollars in sales of its Contaminated Formula Products packaged in containers lined with polycarbonate plastic containing BPA.

108. Under IC 24-5-0.5-3 and IC 24-5-0.5-4, Plaintiff and the Class Members are entitled to a refund of all monies acquired by Defendant by means of the unlawful practices alleged in this Complaint, as well as compensatory damages, including treble damages and attorney's fees.

COUNT II : Violation of State Consumer Protection Laws

109. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein. Each of these Plaintiffs brings this Count on his/her own behalf under the law of the state in which he/she purchased Contaminated Formula Products produced by Defendant on behalf of: (a) all other persons who purchased Contaminated Formula Products produced by Defendant in the same state as Plaintiffs purchased such products; and (b) all other persons who purchased such products in states having similar consumer protection laws.

110. Each Plaintiff and member of the Class is a consumer, purchaser or other person entitled to the protection of the consumer protection laws of the state in which he or she purchased the Contaminated Formula Products produced by Defendant.

111. The consumer protection laws of the state in which each Plaintiff and member of the Class purchased the Contaminated Formula Products declares that unfair or deceptive acts or practices in the conduct of trade or commerce are unlawful.

112. Thirty-seven states and the District of Columbia have enacted statutes designed to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising and that allow consumers to bring private and/or class actions. These statutes are found at:

a. Alaska Unfair Trade Practices and Consumer Protection Act, Ak. Code § 45.50.471, *et seq.*;

b. Arkansas Deceptive Trade Practices Act, Ark. Code § 4-88-101, *et seq.*;

c. California Consumer Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.*, and California's Unfair Competition Law, Cal. Bus. & Prof Code § 17200, *et seq.*;

d. Colorado Consumer Protection Act, Colo. Rev. Stat. § 6-1-101, *et seq.*;

e. Connecticut Unfair Trade Practices Act, Conn. Gen. Stat § 42-110a, *et seq.*;

f. Delaware Deceptive Trade Practices Act, 6 Del. Code § 2511, *et seq.*;

g. District of Columbia Consumer Protection Procedures Act, D.C. Code §§ 28 3901, *et seq.*;

h. Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201, *et seq.*;

i. Georgia Fair Business Practices Act, §10-1-390 *et seq.*;

j. Hawaii Unfair and Deceptive Practices Act, Hawaii Revised Statues § 480 1, *et. seq.*, and Hawaii Uniform Deceptive Trade Practices Act, Hawaii Revised Statutes § 481A-1, *et seq.*;

k. Idaho Consumer Protection Act, Idaho Code § 48-601, *et seq.*;

l. Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1, *et seq.*;

m. Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50 626, *et seq.*;

n. Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110, *et seq.*, and the Kentucky Unfair Trade Practices Act, Ky. Rev. Stat. Ann §§ 365.020, *et seq.*;

o. Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401, *et seq.*;

p. Maine Unfair Trade Practices Act, 5 Me. Rev. Stat. § 205A, *et seq.*, and Maine Uniform Deceptive Trade Practices Act, Me. Rev. Stat. Ann. 10, § 1211, *et seq.*,

q. Maryland Consumer Protection Act, Md. Com. Law Code § 13-101, *et seq.*;

r. Massachusetts Unfair and Deceptive Practices Act, Mass. Gen. Laws ch. 93A;

s. Michigan Consumer Protection Act, §§ 445.901, *et seq.*;

t. Minnesota Prevention of Consumer Fraud Act, Minn. Stat §§ 325F.68, *et seq.*; and Minnesota Uniform Deceptive Trade Practices Act, Minn. Stat. § 325D.43, *et seq.*;

u. Mississippi Consumer Protection Act, Miss. Code Ann. §§ 75-24-1, *et seq.*;

v. Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.010, *et seq.*;

w. Montana Unfair Trade Practices and Consumer Protection Act, Mont. Code §30-14-101, *et seq.*;

x. Nebraska Consumer Protection Act, Neb. Rev. Stat. §59 1601, *et seq.*, and the Nebraska Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. § 87-301, *et seq.*;

y. Nevada Trade Regulation and Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.*;

z. New Hampshire Consumer Protection Act, N.H. Rev. Stat. § 358-A:1, *et seq.*;

aa. New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8 1, *et seq.*;

bb. New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57 12 1, *et seq.*;

cc. New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.*;

dd. North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51 15 01, *et seq.*;

ee. Oklahoma Consumer Protection Act, Okla. Stat. 15 § 751, *et seq.*;

ff. Oregon Unfair Trade Practices Act, Rev. Stat § 646.605, *et seq.*;

gg. Rhode Island Unfair Trade Practices And Consumer Protection Act, R.I. Gen. Laws § 6-13.1-1, *et seq.*;

hh. South Carolina Unfair Trade Practices Act, S.C. Code Laws § 39-5-10, *et seq.*;

ii. South Dakota's Deceptive Trade Practices and Consumer Protection Law, S.D. Codified Laws §§ 37 24 1, *et seq.*;

gg. Vermont Consumer Fraud Act, Vt. Stat. Ann. tit.9, § 2451, *et seq.*;

kk. Washington Consumer Fraud Act, Wash. Rev. Code § 19.86.010, *et seq.*;

ll. West Virginia Consumer Credit and Protection Act, West Virginia Code § 46A-6-101, *et seq.*;

mm. Wisconsin Deceptive Trade Practices Act, Wis. Stat. §§ 100.18, *et seq.*

113. The Contaminated Formula Products produced by Defendant constitutes products to which these consumer protection laws apply.

114. In the conduct of trade or commerce regarding its production, marketing and sale of Contaminated Formula Products, Defendant engaged in one or more unfair or deceptive acts or practices, including but not limited to failing to disclose or adequately disclose the following material facts, inter alia: (1) that its Contaminated Formula Products contained BPA; (2) that numerous scientific studies performed by, among others, government scientists and university laboratories, found health concerns associated with BPA; (3) that BPA leaching is accelerated by heat; and (4) that the industry studies that were provided to the FDA by the chemical companies that manufacture BPA, and upon which Defendant relies in representing that BPA is safe, are flawed.

115. Defendant's labeling, statements, advertisements, representations and omissions were deceptive and/or likely to deceive.

116. Defendant knew or should have known that its statements, advertisements, representations and omissions were false, untrue and misleading.

117. Defendant used or employed such deceptive and unlawful acts or practices with the intent that these Plaintiffs and members of the Class rely thereon.

118. Plaintiffs and the other members of the Class did so rely.

119. Each Plaintiff and member of the Class purchased Contaminated Formula Products produced by Defendant who falsely represented the healthiness and safety of the Contaminated Formula Products. Plaintiffs and members of the Class would not have purchased the Contaminated Formula Products but for the deceptive and unlawful acts of Defendant.

120. As a result of Defendant's conduct, Plaintiffs and members of the Class were damaged.

121. Defendant's conduct showed complete indifference to or conscious disregard for the rights and safety of others such that an award of punitive and/or statutory damages is appropriate

COUNT III: Breach of Express Warranty

122. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein. Each of the Plaintiffs brings this Count on his/her own behalf under the law of the state in which he/she purchased Contaminated Formula Products produced by Defendant on behalf of: (a) all other persons who purchased Contaminated Formula Products produced by Defendant in the same state; and (b) all other persons who purchased such products in states having similar laws regarding express warranty.

123. Defendant's representation that the Contaminated Formula Products are safe and healthy is an affirmation by Defendant that the Contaminated Formula Products are safe, healthy and generally fit for human use. In fact, Defendant's sale of the Contaminated Formula Products itself is a representation that it believes that they are safe for use.

124. Defendant's representations and insinuations regarding the fitness and safety of the Contaminated Formula Products are made to Plaintiffs and members of the Class at the point of purchase, are part of the description of the goods and the bargain upon which they are offered for sale and purchased by Plaintiffs and members of the Class.

125. In addition or in the alternative, Defendant's representations are made to induce Plaintiffs and members of the Class to rely on such representations, and Plaintiffs and members of the Class did so rely on said representations as a material factor in his/her decision to purchase the Contaminated Formula Products. Plaintiffs and the members of the Class would not have purchased the Contaminated Formula Products but for these representations and warranties.

126. The Contaminated Formula Products produced by Defendant did not, in fact, meet with descriptions Defendant made about the health benefits and safety of the products.

127. At all times relevant to this action, Defendant falsely represented its Contaminated Formula Products were fit for human use when they were not, and falsely represented the other characteristics of the Contaminated Formula Products in breach of these express warranties.

128. At all times relevant to this action, Defendant made false representations in breach of its express warranties and in violation of state express warranty laws, including:

a. Ak. St. § 42.02.313.
b. Ariz. Rev. Stat. Ann. § 47-2313.
c. Ark. Code Ann. § 4-2-313.
d. California Commercial Code § 2313.
e. Colo. Rev. St. § 4-2-313.
f. Conn. Gen. Stat. Ann. § 42a-2-313.
g. D.C. Stat. § 28:2-313.
h. Haw. Rev. Stat. § 490:2-313.
i. Ind. Code § 26-1-2-313.
j. Kansas Stat. Ann. § 84-2-313.
k. La. Civ. Code. Ann. Art. 2520
l. 11 Maine Rev. Stat. Ann. § 2-313.
m. Mass. Gen. Laws Ann. 106 § 2-313.
n. Minn. Stat. Ann. § 336.2-313.
o. Miss. Code Ann. § 75-2-313.
p. Missouri Rev. Stat. §400.2-313.
q. Mont. Code Ann. 30-2-313.
r. Neb. Rev. Stat. § 2-313.
s. Nev. Rev. Stat. §104.2313.
t. N.H. Rev. Stat. § 382-A:2-313.
u. N.J. Stat. Ann. 12A:2-313.

v. N.M. Stat. Ann. § 55-2-313.

w. N.Y. U.C.C. Law § 2-313.

x. N.C. Gen. Stat. Ann. § 25-2-313.

y. Okla. Stat. Ann. Tit. 12A, § 2-313.

z. Or. Rev. Stat. § 72.3130.

aa. Pa. Stat. Ann. Tit. 13, § 2313.

bb. R.I. Stat. § 6A-2-313.

cc. S.C. § 36-2-313.

dd. S.D. Cod. Laws. § 57A-2-313.

ee. Tenn. Code Ann. § 47-2-313.

ff. Tex. Bus. & Com. Code Ann. § 2.313.

gg. Ut. Code Ann. § 70A-2-313.

hh. Vt. Stat. Ann. § 2-313.

ii. Wa. Ann. 62A.2-313.

jj. W. Va. Code § 46-2-313.

kk. Wyo. Stat. 34.1-2-313.

129. The above statutes do not require privity of contract in order to recover for breach of express warranty.

130. As a result of Defendant's conduct, Plaintiffs and members of the Class were damaged, have suffered injury in fact and have lost money and/or property.

131. Within a reasonable time after they knew or should have known of such breach, Plaintiffs, on behalf of themselves and members of the Class, placed Defendant on notice thereof.

COUNT IV: Breach of Implied Warranty of
Merchantability and Fitness for a Particular Purpose

132. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein. Each of the Plaintiffs brings this Count on his/her own behalf under the law of the state in which he/she purchased Contaminated Formula Products produced by Defendant on

behalf of: (a) all other persons who purchased Contaminated Formula Products produced by Defendant in the same state; and (b) all other persons who purchased such products in states having similar laws regarding implied warranties of merchantability and fitness for a particular purpose.

133. Plaintiffs and members of the Class purchased Contaminated Formula Products produced by Defendant for the ordinary purposes of Contaminated Formula Products, assuming that it was, in fact, safe to consume them. Plaintiffs and the members of the Class relied on Defendant's skill and judgment to select and furnish suitable goods for that purpose.

134. Defendant held itself out as possessing, and did, possess expertise, skill and knowledge superior to consumers including Plaintiffs and members of the Class, who had a right to rely thereon.

135. By marketing the Contaminated Formula Products for sale, Defendant impliedly warranted that such products were, in fact, safe for ordinary use by children and infants.

136. By the acts set forth in detail above, Defendant warranted that the Contaminated Formula Products were safe and healthy, but intentionally omitted, suppressed, and withheld material information regarding risks associated with BPA found in its Contaminated Formula Products. Plaintiffs and the members of the Class bought the Contaminated Formula Products relying on Defendant's skill, judgment and representations. However, Defendant's Contaminated Formula Products are not free from risk of harmful exposure to BPA, as set forth in detail above.

137. At the time of the sales, Defendant had reason to know the particular purpose for which its goods were being offered and acquired, and that Plaintiffs and the members of the Class were relying on Defendant's skill and judgment to select and furnish suitable and safe

goods for that purpose. Accordingly, there was an implied warranty that the goods were fit for this purpose.

138. However, Defendant breached this warranty implied at the time of sale by providing goods that are/were unsuitable for the purpose for which they were made and purchased because the Contaminated Formula Products sold were not free from risk of harmful exposure to BPA.

139. As such, the Contaminated Formula Products produced and sold by Defendant were not fit for their ordinary purpose.

140. Defendant's conduct breached its implied warranties regarding the Contaminated Formula Products sold under state implied warranty laws including:

a. Ak. St. § 45.02.314 and § 45.02.315.
b. Cal. Comm. Code § 2314.
c. Co. Rev. Stat. § 4-2-314 and § 4-2-315.
d. 6 Del. C. § 2-314 and § 2-315.
e. D.C. Stat. § 28:2-314 and § 28:2-315.
f. Haw. Rev. Stat. § 490:2-314 and § 490:2-315.
g. Ind. Code § 26-1-2-314 and § 26-1-2-315.
h. La. Civ. Code Ann. Art. 2524.
i. 11 Maine Rev. Stat. Ann. § 2-314 and § 2-315.
j. Md. Com. Law Code Ann. § 2-314 and § 2-315.
k. Mass. Gen. Laws Ann. 106 § 2-314 and § 2-315.
l. Mich. Comp. Laws Ann. 440.2314 and 440.2315.
m. Minn. Stat. Ann. § 336.2-314 and §336.2-315.
n. Miss. Code Ann. § 75-2-314 and § 75-2-315.
o. Missouri Rev. Stat. 400.2-314 and 400.2-315.
p. Mont. Code Ann. 30-2-314 and 30-2-315.
q. Neb. Rev. Stat. § 2-314 and § 2-315.
r. Nev. Rev. Stat. 104.2314 and 104.2315.
s. N.H. Stat. Ann. § 382-A:2-314 and § 382-A:2-315.

t. N.J. Stat. Ann. 12A:2-314 and 12A:2-315.

u. N.M. Stat. Ann. § 55-2-314 and § 55-2-315.

v. N.D. Stat. 41-02-31 and 41-02-32.

w. Ohio Rev. Code Ann. § 1302.27 and § 1302.28.

x. Okla. Stat. Ann. tit. 12A, § 2-314 and § 2-315.

y. Pa. Stat. Ann. tit. 13, § 2314 and §2315.

z. S.C. § 36-2-314 and § 36-2-315.

aa. S.D. Cod. Laws. § 57A-2-314 and § 57A-2-315.

bb. Tex. Bus. & Com. Code Ann. § 2.314 and § 2.315.

cc. Ut. Code Ann. § 70A-2-314 and § 70A-2-315.

dd. Va. Code Ann. § 8.2-314 and § 8.2-315.

ee. W. Va. Code § 46-2-314 and § 46-2-315.

ff. Wyo. Stat. 34.1-2-314 and 34.1-2-315.

141. These states do not require privity of contract in order to recover for breach of implied warranty.

142. As a result of Defendant's breach of their implied warranties, Plaintiffs and members of the Class have been damaged.

143. Within a reasonable time after they knew or should have known of such breach, Plaintiffs, on behalf of themselves and members of the Class, placed Defendant on notice thereof.

COUNT V: Intentional Misrepresentation

144. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein. Each of the Plaintiffs brings this Count on his/her own behalf under the law of the state in which he/she purchased Contaminated Formula Products produced by Defendant on behalf of: (a) all other persons who purchased Contaminated Formula Products produced by Defendant in the same state; and (b) all other persons who purchased such products in states having similar laws regarding intentional misrepresentations.

145. Defendant has represented to the public, including Plaintiffs, by promoting, marketing, advertising, packaging, labeling and other means or by intentional omission, that its Contaminated Formula Products have the characteristics, ingredients, and qualities that they do not have, specifically, that the Contaminated Formula Products were healthy and safe for use, or have concealed and/or omitted relevant and material facts about the characteristics of those products.

146. Defendant's misrepresentations and omissions were material.

147. Defendant's representations were untrue in that the Contaminated Formula Products were not free from risk of harmful exposure to BPA.

148. At the time Defendant made the representations and omissions herein alleged it knew the representations were false.

149. Defendant made the omissions and misrepresentations herein alleged with the intention of depriving Plaintiffs and Class members of property or otherwise causing injury, and have committed fraud.

150. Plaintiffs and others believed and relied on Defendant's uniform omissions, promotions, marketing, advertising, packaging and labeling of the Contaminated Formula Products, and, in justifiable reliance thereon, purchased the Contaminated Formula Products.

151. As a proximate result of these acts, Plaintiffs and other consumers were induced to purchase products that they would not have purchased but for the misrepresentations and/or omissions and spent an amount to be determined at trial.

152. Plaintiffs and the Class in purchasing, using, and consuming the Contaminated Formula Products as herein alleged, did rely on Defendant's above representations, all to their detriment.

153. As a result of Defendant's conduct, Plaintiffs and Class members were damaged and are therefore entitled to compensatory damages, multiple damages, punitive damages and equitable relief.

COUNT VI: Negligent Misrepresentation

154. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein. Each of the Plaintiffs brings this Count on his/her own behalf under the law of the state in which he/she purchased Contaminated Formula Products produced by Defendant on behalf of: (a) all other persons who purchased Contaminated Formula Products produced by Defendant in the same state; and (b) all other persons who purchased such products in states having similar laws regarding negligent misrepresentation.

155. Defendant owed a duty to Plaintiffs and members of the Class to exercise reasonable care in making representations about the health, safety and fitness for use of their Contaminated Formula Products.

156. Defendant negligently and recklessly made such representations and omitted to disclose material facts to potential customers and the general public through uniform misrepresentations, non-disclosure and concealment through promotion, marketing, advertising, packaging, labeling and other means or by omission by Defendant or at their direction.

157. Defendant's representations and omissions regarding the safety and health benefits of their plastic bottle products were material.

158. Defendant's mislabeling, misrepresentations and non-disclosures were intended to influence consumers' purchasing decisions.

159. Plaintiffs and members of the Class reasonably relied on Defendant's uniform promotion, marketing, advertising, packaging and labeling of its Contaminated Formula

Products, which misrepresented and omitted crucial facts and, in justifiable reliance thereon, purchased the Contaminated Formula Products.

160. Defendant knew or should have known that Plaintiffs and members of the Class relied upon the labeling, representations and omissions of Defendant.

161. Defendant's representations and omissions regarding the safety and healthiness of its Contaminated Formula Products were false and misleading as alleged above.

162. As a result of these misrepresentations, omissions and concealment, Plaintiffs and members of the Class have been damaged in an amount to be proven at trial.

163. As a result of Defendant's conduct, Plaintiffs and Class members were damaged and are therefore entitled to compensatory damages, multiple damages, and equitable relief.

COUNT VII: Unjust Enrichment

164. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein. Each of the Plaintiffs brings this Count on his/her own behalf under the law of the state in which he/she purchased Contaminated Formula Products produced by Defendant on behalf of: (a) all other persons who purchased Contaminated Formula Products produced by Defendant in the same state; and (b) all other persons who purchased such products in states having similar laws regarding unjust enrichment.

165. Defendant benefited from monies received from the purchases made by Plaintiffs and members of the Class of Contaminated Formula Products produced by Defendant.

166. Under the circumstances, it would be inequitable for Defendant to retain the above-described benefits.

167. As a result of Defendant's unjust enrichment, Plaintiffs and members of the Class suffered losses in an amount to be determined at trial and seek full disgorgement and restitution of Defendant's unjust enrichment.

JURY TRIAL DEMANDED

168. Plaintiff and the proposed Class demand a trial by jury for all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and the Class members request that the Court enter an order or judgment against Defendant including the following:

A. Certification of the action as a Class Action pursuant to Rule 23(b)(3) or 23(b)(2) of the Federal Rules of Civil Procedure, and appointment of Plaintiffs as Class Representatives and their counsel of record as Class Counsel;

B. Damages in the amount of monies paid for Defendant's offending Contaminated Formula Products and/or other consequential or incidental damages;

C. Actual damages, statutory damages, punitive or treble damages, and such other relief as provided by the statutes cited herein;

D. Pre-judgment and post-judgment interest on such monetary relief;

E. Equitable relief in the form of restitution, to restore monies received by Defendant as a result of the unfair, unlawful and/or deceptive conduct alleged herein;

F. Injunctive relief barring Defendant from continuing its use of BPA in its Contaminated Formula Products in the manner described herein;

G. The costs of bringing this suit, including reasonable attorneys' fees; and

H. All other relief to which Plaintiffs and members of the Class may be entitled at law or in equity.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 15, 2009, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will automatically send a notice of electronic filing to all persons registered for ECF as of that date.

/s/ *Thomas V. Bender*